UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,199	05/31/2001	Jean-Charles Schwartz	P06853US00/L	8229

881 7590 08/21/2003

LARSON & TAYLOR, PLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER	
SEAMAN, D MARGARET M	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/622,199	Applicant(s) SCHWARTZ ET AL.	
	Examiner D. Margaret Seaman	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-122 and 124-127* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-122 and 124-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This application was filed 31 May 2001 and is a 371 of PCT/EP99/05744, filed 29 July 1999. Claim 123 has been canceled per paper #21, dated 8 August 2003. Claims 89-122 and 124-127 are before the Examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The rejection of claims 89-122 and 124-127 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as stated in paper #20, dated 8 May 2003, is upheld.

Specifically, the claims remain ambiguous due to many things in claim 89. The remaining claims are dependent from claim 89. Claim 89 is ambiguous due to the newly added language. The claim is drawn to a method of treating diseases or conditions. However, how are "urogenital system", "digestive tract", "skin", "respiratory", "bronchi", "conditions requiring sedative" and "tranquilizing" selected diseases or conditions? Is "analgesic" meant to be the treatment of pain? It is not clear as to how "tranquilizing", "anti-stress" and "sedative" differ from each other. "Central

nervous system disorders" includes and overlaps with "CNS disorders in aged persons". Psychotropic and nootropic disorders/conditions appear to overlap considerably with each other. Also, Psychotropic and nootropic appear to overlap with wakefulness, attention, memory and mood disorders. What is "rheumatic conditions of inflammatory conditions of the eye"?

Specifically, claim 125 depends from claim 89 and states "the central nervous disorders". However, claim 89 states either "central nervous system disorders" or "CNS disorders in aged persons". It is unclear as to which is being referred to due to neither being "central nervous disorders".

Specifically, claim 126 is unclear because it does not have proper antecedent basis. "The nootropic effects" is not found in claim 89. Claim 89 appears to be drawn to nootropic disorders and not nootropic effects.

Clarification is required.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of claims 89-122, 124-126 and now claim 127 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated in paper #20, is upheld. As previously stated, it is not seen where the instant specification enables the ordinary artisan to use the instant invention to treat central nervous system disorders, providing psychotropic effects, providing nootropic effects, treating psychosomatic disorders and other conditions such as obesity. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: The claims are drawn to a method of treatment of many diseases and conditions somehow linked to the ligand of the histamine H3 receptors by using a multitude of compounds having a nitrogen atom as a common core.

2) The nature of the invention: The nature of the invention is the treatment of diseases/conditions linked to the ligand of histamine H3 receptors and the conditions linked to this range from CNS disorders to obesity to stress.

3) The state of the prior art: The prior art does not link all the diseases/conditions listed in the claims to a ligand of the histamine H3 receptors.

5) The level of predictability in the art: The predictability in the art is low due to the large differences in the activities compared to the small differences between the structures of the compounds tested.

6) The amount of direction provided by the inventor: There is little direction provided by the inventor other than the specific compounds made in the instant specification.

7) The existence of working examples: There are many example compounds in the specification, however, few have been shown as having activity. Of those compounds tested, the activities vary widely with only minor changes in structure. The declaration provided (paper #18) shows only one compound (#117) and its activity.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The amount of experimentation needed is unexpected due to the little guidance provided by the specification.

Taking all of this into consideration, the specification is not seen to be enabling.

Applicant provided a declaration (paper #18, dated 22 November 2002) disclosing how compound #117, 3-(4-chlorophenyl)propyl-3-piperidinopropyl ether, changes tele-methylhistamine levels. This declaration remains not commensurate in scope for the instant claims 89-122 and 124-127. This declaration enables the one compound #117 to treat diseases and conditions by changing the tele-methylhistamine levels in a patient in need thereof. However, this is not seen as enabling for any and all

compounds having a N atom that are encompassed by the instantly claimed compounds. Also, this declaration does not enable the connection between tele-methylhistamine levels and the diseases and conditions listed in the instant claims. A claim that is limited to the compound of #117 and limited to changing the levels of tele-methylhistamine, having proper support under 35USC 101, would be seen as allowable. All other claims remain as lacking enablement.

Applicants have further given compound examples and ED50 values in paper #21. However, this is not provided in a proper deceleration format nor are these from the specification. The argument states that ID50 values provided show the instant inventions activity. However, the values provided are ED50 values. The test procedures that gives these numbers is not disclosed. Are these values ID50 values or ED50 values? If these ED50 values are from a valid test and do show the instant claimed utility, then they also show the unpredictability between the compounds of the instant Markush. Compounds 1 and 2 differ by piperidine and pyrrolidine and their ED50 values are 6.9 and 3.4: double the activity for such a little variation. The difference between compound 2 (phenyl) and 18 (nitrophenyl) is 3.4 and 1.1. A large difference in activity for a small structural difference.

The rejection of claims 89-122 and 124-127 is upheld.

Conclusion

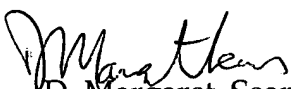
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms